



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 501

[Docket No. FDA-2009-N-0025]

Animal Food Labeling; Declaration of Certifiable Color Additives

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods. FDA is issuing a final regulation in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by requiring, among other things, the listing on food labels of the common or usual names of all color additives required to be certified by FDA. An additional purpose of this final rule is to make these regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The final rule also suggests appropriate terminology for the declaration of certification-exempt color additives on the labels of animal food.

DATES: This rule is effective November 18, 2013.

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SUPPLEMENTARY INFORMATION:

I. Background

The 1990 amendments amended section 403(i) of the FD&C Act to require that certified color additives used in or on a food be declared by their common or usual names. Because section 201(f) of the FD&C Act (21 U.S.C. 321(f)) defines “food” as any article used for food or drink for man or other animals, the changes made to section 403(i) by the 1990 amendments apply to both human and animal foods. In response to this statutory amendment, FDA revised its human food labeling regulations by adding paragraph (k) to § 101.22 (21 CFR 101.22). The proposed and final rules for these regulations were published in the Federal Register on June 21, 1991 (56 FR 28592) and January 6, 1993 (58 FR 2850), respectively.

On November 23, 2009, FDA issued a proposed rule (74 FR 61068) (proposed rule) which proposed a regulation for animal food labels similar to the one made in § 101.22 for human food labels. Specifically, the proposed rule adds paragraph (k) to the animal food labeling regulations at § 501.22 (21 CFR 501.22). This paragraph explains how certified color additives used in animal foods must be declared in the ingredient list, and sets out the various ways that manufacturers may collectively declare certification-exempt color additives in the ingredient list. Proposed § 501.22(k)(1) states that a color additive or the lake of a color additive subject to certification under section 721(c) of the FD&C Act (21 U.S.C. 379(c)) shall be declared by the common or usual name of the color additive as listed in the applicable regulation in part 74 (21 CFR part 74) or part 82 (21 CFR part 82), except that it is not necessary to include the “FD&C”

prefix or the term “No.” in the declaration. However, the term “Lake” shall be included in the declaration for the lake of a certified color additive (e.g., Blue 1 Lake).

Proposed § 501.22(k)(2) states that manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82. The new provision also provides a number of options for collectively declaring the presence in food of the certification-exempt color additives that are listed in part 73 (21 CFR part 73). Color additives not subject to certification may be declared as “Artificial Color,” “Artificial Color Added,” or “Color Added” (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as “Colored with _____” or “_____ color,” the blank to be filled with the name of the color additive listed in the applicable regulation in part 73.

II. Comments

FDA received 14 comments, all from consumers who overwhelmingly supported the proposed rule. These comments approved of the declaration of certified colors in animal food as an aid to consumers in avoiding food allergies and other adverse reactions potentially caused by added colorings. Consumers value this additional information on the label in order to make informed choices about what their animals consume. There were only two comments that opposed the proposal and one comment that suggested additional requirements be adopted.

(Comment 1) One comment described the proposed rule as “frivolous” and stated that if the color additive was approved by FDA for inclusion in an animal food, the specific name of the color additive would not need to be declared. The commenter stated that without added colors the animal food would not be appealing. The comment concluded that adding information on certified colors would not benefit consumers.

The 1990 amendments required the declaration of certified colors on food labels and that requirement applies to animal food as well as human food. FDA is seeking to bring the declaration of certified colors on labels of animal food in line with the labeling of human foods. Twelve of the comments indicated that consumers strongly support these proposed requirements and believe that such information on the label would be valuable to them and would enable them to make informed decisions of their pet food choices, thus demonstrating that this rule is not frivolous and serves to provide desired information to consumers.

(Comment 2) One comment expressed disapproval of the proposed rule claiming that the costs of the rule outweigh the benefits. The comment stated, “In difficult economic times, it seems unwise to impose unknown costs on small businesses without concrete benefits to consumers.” Instead, the comment proposed exempting small businesses employing fewer than 20 employees from the labeling requirements of § 501.22(k)(1) and (k)(2), provided they state on the label “artificial color added.” The comment also stated that the rule did not have “concrete benefits.”

In passing the 1990 amendments, Congress anticipated that declaration of certified colors, and nutrition labeling provisions in general, would impose some substantial compliance costs for large and small businesses (58 FR 2070; January 6, 1993). In the Regulatory Flexibility Analysis of the proposed rule (74 FR 61068 at 61069) we considered the economic impact on small businesses, as well as large firms, and tentatively concluded that at every establishment size, the expected cost of compliance would likely be significantly less than 1 percent of revenues for each label requiring new labeling. We have, therefore, determined that the compliance costs of this final rule are unlikely to have a significant economic impact on a substantial number of small entities and that compliance costs are, in general, reasonable.

Furthermore, this comment's suggestion that businesses with less than 20 employees be exempted from proposed § 501.22(k)(1) and (k)(2) if the phrase "Artificial Color Added" is added to the label fails to negate the compliance costs associated with this final rule. FDA maintains that it is the total process of changing the label (including administrative, graphic, prepress, and engraving activities as well as label inventory loss), and not the actual wording change on the label, that imposes the vast majority of the compliance costs of the rule. The requested exemption would still require those that qualify to make label changes and would only minimally reduce the number of words on the label. Additionally, the requested exemption would likely require that FDA create reporting requirements to allow small businesses to qualify for the exemption based on the number of employees. Thus, the requested exemption would not be expected to meaningfully reduce compliance costs. Due to these reasons, FDA has decided not to include this exemption in the final rule.

Moreover, FDA is decreasing the impact of such compliance costs by adopting a 2-year effective date to allow for depletion of animal food label inventories, and thus, FDA has done everything possible to both satisfy the statutory mandate and reduce the impact on affected businesses.

The consumers that commented on the proposed rule overwhelmingly indicated their support of the rule, and their willingness to incur additional costs in order to have the benefit of more information being declared on the label. One comment in support of the rule stated, "Many pet food manufacturers are already compliant with these new regulations because the FDA had provided informal education to manufacturers in the 1990s, in anticipation of the impending changes under [the 1990 amendments]." Therefore, FDA finds that from the comments received, the public generally perceives that there is a benefit to the proposed rule as adopted.

(Comment 3) One comment that supported the proposed rule suggested that FDA go farther and require that certification-exempt colors, such as cochineal or carmine, be declared on animal food labels. The comment cited concerns regarding the potential for allergic reactions or illness caused by these color additives.

Congress mandated the declaration of certified colors in the 1990 amendments. Certification-exempt colors were not part of the Congressional initiative. However, CVM will work in concert with the Center for Food Safety and Applied Nutrition in evaluating whether additional authority in this area is needed.

As stated previously, other comments received generally supported the proposed rule for a variety of reasons, including the importance of informing consumers about the food they feed their pets. Therefore, as the comments in opposition to the proposed rule did not provide sufficient evidence to cause FDA to alter its provisions, FDA did not amend the provisions of the proposed rule in response to comments and is making no changes to the final regulation.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As discussed more fully in section IV of this document, we have prepared a final regulatory flexibility analysis. This analysis indicates that at every establishment size, the expected one-time cost of compliance would likely be significantly less than 1 percent of average annual revenues for each label requiring new labeling. We have, therefore, determined that the compliance costs of the final rule are unlikely to have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Purpose of Rule

The purpose of this rule is to implement the 1990 Amendments, which required that all food labels list the common or usual names of all color additives that are required to be certified by FDA. FDA published the proposed rule in the November 23, 2009, Federal Register proposing a regulation that would require that the common or usual name of all color additives that are required to be certified by FDA be listed on the label of animal foods. Additionally, the proposed rule suggested how color additives not certified by FDA should be declared on the ingredient list of animal foods. This regulation would amend FDA's animal food regulations to

include certain requirements of the 1990 Amendments, as was previously done with the human food regulations. Because FDA was directed to establish regulations by the 1990 Amendments, the agency lacked a great deal of flexibility in the development of the proposed rule.

B. Comments to the Proposed Rule

FDA received 14 comments to the proposed rule. Most supported the proposed rule, but one comment, which disapproved of the rule, stated that the costs of the rule outweigh the benefits. FDA does not agree with the implication of this comment that the rule is not justified and should not be finalized. Although, for the proposed rule and this final rule, FDA does not have information to quantify and monetize the benefits of the rule, FDA has provided a 2-year effective date in an attempt to reduce the compliance costs of the final rule. As discussed previously, this comment also suggested that businesses with less than 20 employees be exempted from proposed § 501.22(k)(1) and (k)(2) if the phrase “Artificial Color Added” is added to the label. Because the requested exemption would still result in label changes for those that qualify for the exemption, it would only minimally reduce the number of words on the label, and would not be expected to meaningfully reduce compliance costs. Due to these reasons, FDA has decided not to include this exemption in the final rule.

C. Benefits

As stated previously, no comments to the rule contained information or argument that persuaded FDA to amend the codified language of the rule. As such, FDA retains its initial benefits discussion and cost model for this final rule, incorporating updated cost factors where necessary to reflect current conditions. The principal benefit of this rule is that it would provide additional consumer information for purchasers of pet food and other animal food products to consider in making their buying decisions for those animal food products that are not currently

labeled in accordance with the provisions of this final rule. The agency does not have any data with which to quantify the extent to which having this additional information would result in more informed buying decisions by consumers. The rule also would provide some voluntary options for all animal food manufacturers, including options for terminology they can use when declaring certification-exempt color additives on their product labels.

D. Costs

The final rule has an effective date that is 2 years from the date of publication. This time is intended to allow animal food manufacturers some time to deplete their current label inventories as they make the transition to the new label. We do not expect this final rule to require a major label redesign because it would likely only necessitate minor changes in wording on the ingredient list. Many animal food manufacturers are already declaring certified color additives in their labeling by their common or usual name.

The rule would impose some review costs on those animal food manufacturers that use or intend to use certified color additives. Because the vast majority of animal food products that contain certified color additives are pet foods, we limit the costs to review labels for the use of certified color additives to pet food manufacturers. Each of these manufacturers would need to review the labels of its pet food products to determine the current level of compliance with the final rule. Those manufacturers determined not to be in compliance with the final rule would incur additional costs under § 501.22(k)(1) to change the wording of their labels.

Animal feeds for a limited number of production animals, such as animal feeds for certain farm-raised fish and poultry, also contain color additives. However, we believe the color additives used in animal feeds for fish and poultry are generally certification-exempt, because such color additives can produce the desired colors in edible tissues of these animals more

efficiently than certified color additives; currently, no certified color additive is approved to alter the color of the edible tissue of these animals. We did not receive any comments or data on these assumptions on the use of color additives in animal feeds for production animals in general, and in particular, on the use of certified color additives in fish and poultry feeds.

Animal food manufacturers using certification-exempt color additives in their products would only incur additional relabeling costs under § 501.22(k)(2) if they were to revise their labels to use one of the specific terminology options set forth in that provision. Although § 501.22(k)(2) lists specific terms that manufacturers can use when declaring color additives that are exempt from certification (e.g., "Artificial Color" or "Color Added"), the provision also would permit such color additives to be declared using other equally informative terms that make clear that a color additive has been used in the food. An informal survey of labels demonstrated that most manufacturers of animal food products containing certification-exempt color additives are already declaring the presence of these ingredients in a manner that complies with proposed § 501.22(k)(2).¹ We are not aware of any private incentives that would lead these manufacturers to voluntarily change their labels solely for the purpose of adopting one of the terms identified in proposed § 501.22(k)(2), although it is conceivable that some may make such a change as part of a larger effort to change their labels for other reasons, such as to comply with § 501.22(k)(1) or as part of scheduled labeling changes. Because use of the terminology specified in § 501.22(k)(2) is optional and the presence of certification-exempt color additives can instead be declared in other equally informative ways, we do not expect § 501.22(k)(2) to impose any new compliance costs on animal food manufacturers.

¹ Informal survey of pet foods brands taken on April 20, 2007, at one grocery store and one drug store in Anne Arundel County, Maryland, by FDA personnel.

E. Pet food labeling costs

We do not have data sources that can be used to precisely estimate the number of pet food products. For the purpose of this analysis we assume, based on an industry source, that there may be up to 15,000 different brands of pet foods.² Further, we lack extensive data on pet food labels to confidently estimate the number of such labels that are currently consistent with the provisions of the final rule. An informal survey of pet food products for dogs, cats, rabbits, and guinea pigs, however, found that only 13 of the 68 products surveyed had labels that listed color ingredients in a manner that might be determined not to be in compliance with the final rule. Only 1 of the 13 products would definitely be considered out of compliance with the rule, and that was due to its failure to individually identify which of the identified certified color additives were the colors requiring certification and which were the lakes colors requiring certification.

On many of the other 12 product labels, the phrase “and other color(s)” or similar language followed immediately after a list of FDC colors requiring certification. In these cases, we believe it is likely that the phrase is being used to designate colors that do not require certification. However, because we could not rule out the possibility that the phrase “and other color(s)” or a similar phrase was being used to declare colors requiring certification that, therefore, would need to be listed individually by their common or usual name, we included them in the group of pet food product labels that would possibly be out of compliance. Based on the previous reasoning, we project the midpoint of the 12 possible cases of noncompliance represent actual cases of noncompliance with the final rule. Therefore, we project an upper end of the estimated noncompliance range at 7 of the 68 cases in the sample (6 of the possibly

² Veterinary News Network, www.myvnn.com, accessed May 21, 2007 .

noncompliant cases plus the one case that is almost certainly out of compliance), or about 10 percent.

Due to the uncertainty surrounding pet food products in other market niches, as well as those that are imported (all or almost all of those in the informal sample are products that were produced in the United States, although some ingredients may have been imported), it may be proper to account for these products by increasing the possible non-compliance level. However, because of the arguments mentioned previously concerning our likely over estimation of the upper range of our estimate in our informal survey, we have only increased our high-end estimate of products that would not be in compliance with the proposed rule to 15 percent. Although only 1.5 percent of the sample would definitely be out of compliance, to account for some uncertainty we have increased the low end of our compliance range to 5 percent. We estimate current product labeling that would not be in compliance with the proposed rule to range from 750 to 2,250 products, or 5 to 15 percent of the estimated 15,000 different brands of pet food products. We did not receive any comments or data on these assumptions on the number of existing pet food product labels that would need to be modified in this final rule.

We have estimated a cost for the combined effort by pet food industry management to become familiar with the requirements of the rule, plus the effort to determine the compliance status of each of the approximately 15,000 products. We project that, on average, the compliance status of each product could be determined within 15 minutes by an industry compliance officer. In some instances, notably those involving companies with fewer products, the average may be longer, due to the additional time spent on general education and awareness of the rule's requirements being apportioned over fewer products. For those companies with tens or hundreds of product labels, however, the average time to review an individual pet food

ingredient label could easily be less than our estimate of 15 minutes per label. In any case, at 15 minutes per label, the one-time effort to review the 15,000 labels would amount to 3,750 hours. Using the median wage rate of \$34.31 per hour for an industrial production manager (adding 35 percent to account for benefits results in a cost of \$46.32 per hour), the cost of this label review would amount to about \$174,000.³

FDA's Labeling Cost Model presents low, medium, and high cost estimates for all aspects of the label manufacturing process, from the administrative efforts through physical creation of the label, as well as an estimate for the loss of current label inventory.⁴ We do not have specific data on the frequency of scheduled label changes for the pet food industry, but believe it would be similar to the human food industry. The model also includes a field that attempts to show to what extent human food labeling changes can be coordinated with scheduled labeling changes based on the time period within which the additional changes must be made. The model suggests parameters that lead to cost estimates that fall exponentially with the time allowed for labeling changes. The default or suggested percentages in the human foods model for a 2-year effective date are 33 percent for private label products and 67 percent for brand name products. For pet foods, we believe the large majority of products are branded, implying that our estimate of all pet food labels that would have a scheduled label change within the 2-year effective date should be closer to 67 percent than 33 percent (the Labeling Cost Model does not include data for products made by the pet food industry). Further, the general conclusion of a discussion with an industry association was that 1.5 to 2 years is a reasonable estimate for the

³ U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics NAICS 311100 - Animal Food Manufacturing (http://www.bls.gov/oes/2009/May/naics4_311100.htm).

⁴ FDA Labeling Cost Model, Final Report, Revised January 2003, RTI International.

life of a pet food label order, and for large manufacturers it is likely less than 1 year.⁵ Based on these insights and lacking any other data source, we estimate that 60 percent of the pet food ingredient labeling changes could be coordinated with scheduled labeling changes. We invited public comment and data on the extent to which pet food ingredient labeling changes can be coordinated with scheduled labeling changes in the proposed rule, but did not receive any comments addressing this request.

We ran the model with several different human food items as proxies for pet foods, including canned seafood, cereal, flour meal, and bagged snack food, assuming a 2-year effective date for the rule. The resulting total costs (which include label inventory loss) per stockkeeping unit (SKU) varied from low cost estimates for all but the canned seafood around \$800, and with high cost estimates for canned seafood approaching \$4,750. For the purpose of this analysis, we propose to use the median cost estimates from the cereal and canned seafood model results, or a range from about \$1,250 per SKU to about \$3,550 per SKU. For this final rule, FDA has adjusted these costs for inflation by about 4 percent to about \$1,300 per SKU and \$3,700 per SKU.

We project that only 300 to 900 pet food SKUs would be required to undertake an earlier labeling change as a result of this rule. This represents the 40 percent of SKUs that would not be able to coordinate the label change required by this rule with regularly scheduled label changes multiplied by the 750 to 2,250 SKUs that are not expected to be in compliance with the rule. Based on the range of per SKU costs described previously, the additional one-time labeling costs (including inventory loss) would range from \$390,000 to about \$3.3 million. Discounting these costs until the end of the 2-year transition period (at a 7-percent discount rate) results in one-time

⁵ E-mail communication between industry association and FDA personnel on March 8, 2007.

costs of about \$340,000 to \$2.9 million (at a 3-percent rate, the one-time cost would range from \$367,000 to \$3.1 million).

We estimate total pet food industry one-time costs (discounted at 7 percent) to range from about \$510,000 to \$3.1 million, including both the effort to determine compliance with the final rule and the labeling costs for those SKUs that would remain out of compliance after 2 years from the date of publication of the final rule. We do not project any additional annual reporting costs.

F. Analysis of Alternatives

Because section 403(i) of the FD&C Act as amended by the 1990 amendments specifically requires certified color additives used in food to be declared by their common or usual names, we lacked the flexibility to consider other ways to declare certified color additives on the labels of animal food products. Based on the 2-year effective date included in this final rule, total discounted one-time compliance costs would range from about \$510,000 to \$3.1 million. As indicated earlier, the 2-year effective date is to allow for an orderly transition from current label inventory without a significant, additional cost to the animal food products industry. We invited comment on the 2-year effective date. Aside from one comment which suggested that manufacturers take advantage of the 2-year delay in effectiveness of this rule to come into compliance, we received no comments on our assumption that a 2-year effective date would allow for an orderly transition to the new labels.

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to prepare a regulatory flexibility analysis if a rule is expected to have a significant economic impact on a substantial number of small entities. Although we believe it is unlikely that significant economic impacts would occur,

we cannot rule out the possibility completely because of uncertainty in the distribution of the affected products among establishments producing animal food products. The following constitutes the final regulatory flexibility analysis.

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. As stated previously in this analysis, the agency is amending the ingredient labeling regulations for animal feeds and pet foods to require that the common or usual name of all color additives that are required to be certified by FDA be listed on the label. This change codifies in FDA's animal food labeling regulations the requirements of the 1990 Amendments, as was previously done for the food product labels for humans.

The Regulatory Flexibility Act also requires a description of the small entities that would be affected by the rule, and an estimate of the number of small entities to which the rule would apply. Although some 2007 Census data are available, they do not at this time include the level of detailed information that FDA used from the 2002 Census for this part of the analysis of the proposed rule. Accordingly, FDA relies on the 2002 Census data for the analysis of the final rule. When available, 2007 Census data are also included to show that the number of establishments and companies has not changed enough to meaningfully affect the conclusions of the analysis.

Dog and cat food manufacturers are classified in the North American Industrial Classification System (NAICS) under industry code 311111 – Dog and Cat Food Manufacturing. Census data from 2002 in this category show that 175 companies with 242 establishments make dog and cat foods in the United States (198 companies and 264 establishments in 2007). NAICS industry code 311119 is identified as Other Animal Food Manufacturing. The 2002 Census data for this category reported a total of 1,042 companies with 1,567 establishments (982 companies

and 1,489 establishments in 2007). At least 629 of these establishments, however, prepared feeds for beef cattle, dairy cattle, swine, poultry (other than chickens and turkeys), and other minor production animal species. These establishments manufacture animal feed for production animals such as cattle and swine that ordinarily would not include any color additives in their products. This reduces the number of establishments in industry code 311119 that are subject to § 501.22(k)(1) to 938.

We have not reduced the number of establishments any further to account for the 350 establishments that manufacture feed or feed ingredients for chickens and turkeys, fish species, and other minor species, which are the types of products that we believe are more likely to contain a color additive to aid in their marketability. Based on our understanding that feed or feed ingredients for chickens and turkeys, fish, and some other minor species typically do not contain color additives requiring certification, we believe that manufacturers of these products would only be minimally affected by proposed § 501.22(k)(1), if at all. However, since we cannot rule out the possibility that they would, at some point in the future, use a color additive requiring certification, we do not exclude them from the total of 938 establishments.

For the final rule, FDA includes the 1,303 non-employer establishments in NAICS 31111 (Animal Food Manufacturing) in 2008. Because many of these establishments may not manufacture products that would be affected by this rule, including all 1,303 establishments in the total results in an upper bound to the range of establishments. In total, this demonstrates that the number of establishments manufacturing dog, cat, and production animal foods that could be affected by § 501.22(k)(1) may be as large as 2,483 establishments (242 + 938 + 1,303). However, because the estimate of total SKUs affected by the rule only ranges up to 2,250, the

number of total establishments could not be more than 2,250, and is likely lower since some establishments may have more than one SKU affected by the rule.

The Small Business Administration defines businesses in NAICS categories 311111 and 311119 as small entities if they employ less than 500 employees. Census data show that only one establishment with NAICS code 311111 employs 500 or more employees, and that no establishments within NAICS code 311119 employ 500 or more employees. By definition, all the non-employer establishments have fewer than 500 employees. The existence of some multi-establishment companies in NAICS codes 311111 and 311119 would likely increase the number of companies that would not meet the definition of a small entity because companies composed of more than one establishment are likely to have more employees. Nonetheless, we would expect that a large number of the upper bound of 2,250 establishments that manufacture dog food, cat food, or other animal food that might contain a color additive requiring certification would meet the criteria to be considered small businesses.

Census Data on industry shipments for dog and cat food manufacturers are not available for establishments with one to four employees in 2002. For those establishments with 5 to 9 employees, and those with 10 to 19 employees, the average annual value of shipments, adjusted for inflation, ranges from \$4.06 to \$5.01 million. For all establishments with 20 or more employees, it is much greater. If a manufacturer composed of only one establishment of five to nine employees had to undertake one product relabeling due to this rule, the one-time cost of this effort would represent only about 0.09 percent of average annual revenues. Those establishments with 10 to 19 employees could have 13 SKUs needing relabeling before their one-time costs equal 1 percent of average annual revenues, while establishments with 20 or more

employees could have more than 60 SKUs needing relabeling before their one-time costs equal 1 percent of average annual revenues.

For those establishments with one to four employees that manufacture other animal foods, the average annual value of shipments is about \$1.15 million. The average value of shipments for establishments in this industry with five or more employees is greater than \$4.7 million. An average company composed of one establishment with one to four employees would expend 0.32 percent of its revenues for the cost of relabeling one SKU as a result of this rule. Establishments with 5 to 9 employees and those with 10 to 19 employees could have 13 and 29 SKUs requiring relabeling after 2 years, respectively, before their one-time costs would account for 1 percent of average annual revenues. All larger establishments could have 59 SKUs requiring relabeling after 2 years before their one-time costs would account for 1 percent of average annual revenues.

Although the data shows that the cost for relabeling one SKU would not likely represent a significant burden on a substantial number of small companies, we do not have data on either the number of affected animal food products manufactured by establishments or firms of any size, or the distribution of those animal food products that would not have met the requirements of the rule within 2 years of the publication of this final rule. That being the case, we must allow for the possibility, however unlikely, that the rule could have a significant impact on a substantial number of small firms.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The previous analysis shows that at every establishment size, the expected one-time cost of compliance would be significantly less than 1 percent of average annual revenues for each SKU requiring new labeling. The estimated

number of SKUs requiring new labeling makes it unlikely that their distribution among establishments would result in any establishment incurring compliance costs greater than 1 percent of revenues. The agency believes, therefore, that this final rule would be unlikely to have a significant economic impact on a substantial number of small entities.

V. Environmental Impact

The agency has determined that establishment of this labeling requirement would not increase the existing levels of use or change the intended uses of color additives or their substitutes. Therefore, under 21 CFR 25.30(k), this final rule is determined to be categorically excluded from the need to prepare an environmental assessment or an environmental impact statement.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State law conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts “any requirement for the labeling of food of the type required by * * * [21 U.S.C. 343(i)(2)] * * * that is not identical to the requirement of such section * * *” 21 U.S.C. 343–1(a)(2). This final rule creates requirements for declaring the presence of certified color additives on the labels of animal food, including animal feeds and pet foods under 21 U.S.C. 343(i)(2).

VII. Paperwork Reduction Act of 1995

In the Federal Register of November 23, 2009 (74 FR 61068 at 61072), FDA published a proposed rule and invited comments on, among other things, the proposed collection of information.

In response to this Federal Register notice, FDA did not receive any comments regarding the information collection requirements contained in this final rule. In response to OMB's request that the Agency describe how it has maximized the practical utility of this collection and minimized the burden, an explanation has been provided elsewhere in the preamble of this final rule (section III of this document).

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish notice in the Federal Register, announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number.

Title: Animal Food Labeling: Declaration of Certifiable Color Additives.

Description: FDA is revising its regulations in response to the 1990 amendments which amended the FD&C Act by requiring, among other things, the listing on food labels of the common and usual names of all color additives required to be certified by FDA. An additional purpose of this amendment is to make these regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The final rule also suggests appropriate terminology for the declaration of certification-exempt color additives on

the labels of animal food. Thus, FDA estimates the burden for this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (In Hours)	Total Hours	Total Capital Costs
501.22(k)(1)	2,250	6.67	15,000	0.25	3,750	\$3,100,000 ²
501.22(k)(2)	2,250	0.2	450	0.25	112.5	\$1,500,000

¹There are no operating and maintenance costs associated with this collection of information.

²Because the range was \$510,000 to \$3.1 million, FDA has chosen to show the higher figure here.

The numbers for § 501.22(k)(1) in table 1 of this document were taken from the Analysis of Impacts section of this document (section III of this document). The total number of establishments manufacturing dog, cat, and other non-production animal foods that could be subject to this final rule is estimated at 2,250. The annual frequency per response (6.67) is derived by dividing the 15,000 annual responses (i.e., labels) by the number of establishments (2,250). The total hours (3,750) is derived by multiplying the number of total annual responses (15,000) by 15 minutes (0.25 per response). Due to the proposed two year delay in the effective date of the final rule, the total capital costs range from \$510,000 to \$3.1 million, and operating and maintenance costs were estimated to be zero.

Final § 501.22(k)(2) states the appropriate terminology for the declaration of certification-exempt color additives on the ingredient list of labels of animal food. Although the suggested appropriate terminology for labels for declaration of colors exempt from certification is optional and offers some flexibility to a manufacturer in terms of how to declare such color additives on its ingredient label, it is possible that some may voluntarily adopt the language

specified in § 501.22(k)(2) when they are already relabeling their animal food products for other reasons such as for marketing purposes. The census data show up to 938 establishments produce animal feeds that may contain color additives exempt from certification. These additives may also be used at the 242 dog and cat food establishments in the United States, and any of the 1,303 non-employer establishments. We do not have data that can be used to estimate the number of product labels that will be voluntarily changed at the 2,250 establishments as a result of §501.22(k)(2).

However, our analysis of the required changes for § 501.22(k)(1) estimated that about 6 percent of the products would require label changes after the 2-year effective date has passed (15 percent of labels that are currently out of compliance with proposed §501.22(k)(1) times the 40 percent of those that would remain out of compliance after regular label changes occurring over 2 years). We assume that management would choose to make fewer voluntary label changes than required label changes. For our analysis, we assume that only one-half as much, or 3 years of these products, undergo voluntary label changes as in § 501.22(k)(2). This would result in 0.2 label changes per establishment for § 501.22(k)(2), or 450 label changes over the 2,250 establishments.

The hours per response for label review to determine compliance with the rule and the appropriate language to put on the label is estimated at 0.25 hours, which compares to the time allotted for animal food labels containing certified colors. The annual cost of label review is the hourly wage of an industrial production manager (\$44.24) times 0.25 hours per response times the number of labels.

The upper-bound estimate of relabeling costs for the remaining labels

(i.e., those reviewed for compliance with the proposed rule), is \$3,350 per SKU. The total one-time cost of § 501.22(k)(2) would, therefore, be the cost of label review plus the cost of changing 450 labels as part of normal business practices, for an estimated total of approximately \$1.5 million. The total hours spent, as shown in table 1 of this document, are 112.5 (450 times 0.25).

List of Subjects in 21 CFR Part 501

Animal foods, Labeling, Specific animal food labeling requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 501 is amended as follows:

PART 501--ANIMAL FOOD LABELING

1. The authority citation for 21 CFR part 501 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 501.22 is amended by adding paragraph (k) to read as follows:

§ 501.22 Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

* * * * *

(k) The label of an animal food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section.

(1) A color additive or the lake of a color additive subject to certification under section 721(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the “FD&C” prefix or the term “No.” in the declaration, but the term “Lake” shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). Manufacturers may

parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as “Artificial Color,” “Artificial Color Added,” or “Color Added” (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as “Colored with _____” or “_____ color,” the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

Dated: November 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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